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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,268	03/29/2004	Jeffrey William Moehlenbruck	2103.013882/SBI-064-DIV	2977

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,268	MOEHLENBRUCK ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-124* is/are pending in the application.

4a) Of the above claim(s) *60-81 and 103-124* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of Group II, claims 82-102, in the reply filed on February 7, 2007 is acknowledged.

Claims 60-81, 103-124 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 82-102 are currently under examination.

Priority: The priority date is April 7, 2000.

It is noted that the instant specification contains support for a cross-linked fluid matrix of cross-linked nucleus pulposus tissue (Spec. p. 12 Example I). The instant claims recite an intervertebral disc implant comprising nucleus pulposus tissue. Therefore, the "implant" as recited in the instant claims is believed to also include and/or encompass a "matrix" structure.

Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 82-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 82, 101, 102 recite an intervertebral disc regenerating material. There is no support in the specification for an intervertebral disc regeneration material. Therefore, this constitutes as a new matter rejection. Claims 83-100 are merely rejected for depending from a rejected base claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85, 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 85 and 87 recite denaturing at least portion of the nucleus pulposus and degrading at least portion of the nucleus pulposus tissue, respectively. It is unclear what is the difference between denaturation and degradation. Further, it is unclear how one of ordinary skill would denature or degrade a portion of the tissue without some type of separation step. Otherwise, the entire tissue would be denatured or degraded. Further clarification is requested.

Claim 92 recites at least one protein of the nucleus pulposus tissue. The claim is indefinite because it is unclear which protein of the nucleus pulposus tissue the claim is reciting.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 82-88, 91-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397; previously cited) in view of Ferree (US 6352557). Mechanic discloses a process for cross-linking a proteinaceous material, including collagen, collagen fibrils, and collagen matrices (col. 4 lines 15-16). According to Mechanic, the term proteinaceous material includes both proteins such as collagen and protein-containing materials such as tissue (col. 4 lines 19-20). Proteinaceous materials soaked in a first media solution and irradiated in a second are better cross-linked, show improved mechanical properties and decreased susceptibility to proteolytic degradation (col. 5 lines 1-4). Mechanic discloses solutions of high osmolality are generally used for the first media solution, i.e. sodium, chloride, potassium buffers, and Good's buffers, where in the osmolality have been increased by addition of a solute, such as sucrose (col. 5 line 10). In working examples 1-10, Mechanic discloses proteinaceous materials from different sources to be crosslinked, including pericardium tissue, collagen fibrils, and collagen (col. 8-13). In example 8, rat type I collagen was divided into six samples and each sample was placed in a dialysis bag with 300 mg NaCl (col. 12 line 35-37). Samples 5-6 were dialyzed into phosphate buffered saline pH 7.4 including 50% sucrose, and 0.2% methylene blue (col. 12, lines 40-41) and then exposed to a white floodflight while holding the temperature between 8° and 12°C (col. 12, lines 45-50). Mechanic does not teach nucleus pulposus tissue or an intervertebral disc regenerating material.

Ferree discloses autograft nucleus pulposus cells are harvested, cultured, then added to nucleus pulposus extracellular matrix obtained from recently deceased humans or animals (col. 1 lines 60-65). The combined nucleus pulposus material is then introduced into the injured or disease intervertebral disc (col. 2 lines 1-5). The engineered disc tissue may be morselized and

injected into the disc with a needle and syringe (col. 2 lines 5-10). Further, Ferree discloses additional therapeutic substances, such as tissue growth factors, can be added to the engineered nucleus pulposus matrix (col. 3 lines 36-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Mechanic by substituting the engineered nucleus pulposus material of Ferree for the collagen (fibrils) used in Mechanic (claims 82-88, 91-100). The motivation to do so is given by Ferree, which teaches an engineered nucleus pulposus matrix can be implanted into a recipient to treat degenerative intervertebral disc disease, and Mechanic, which teaches that cross-linking tissue and/or collagen results in a stable, bio-product that resists in vivo degradation and calcification when implanted.

It would also have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional therapeutic substance, i.e. TGF-β, to the nucleus pulposus matrix manufactured by the method of Mechanic in view of Ferree (claims 101-102). The motivation to do so is given by Ferree, which teaches that additional therapeutic substances can be added to the nucleus pulposus implant and may be beneficial to the recovery of the recipient.

Claims 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397; previously cited) in view of Ferree (US 6352557) in view of Moore et al. (US 6350732; IDS). The teachings of Mechanic and Ferree are outlined above. Neither Mechanic nor Ferree teach extracting lipids from a collagenous tissue sample.

Moore et al. teach a method for extracting lipids from collagenous tissue samples for the purpose of storing and preserving the tissue sample and the product of that method (col. 1 lines 29-35).

It would have been obvious to one of ordinary skill in the art to extract lipids from the nucleus pulposus matrix manufactured by the method of Mechanic in view of Ferree (claims 89-90). The motivation to do so is given by Moore et al., which teaches that extracting lipids from collagenous tissue samples will allow the product to be better preserved and stored for longer periods of time. One of ordinary skill would recognize that a better preserved nucleus pulposus matrix would cause less complications when implanted in the body.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 14, 2007

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER